

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

ASTRAZENECA PHARMACEUTICALS  
LP, ASTRAZENECA UK LIMITED, and  
ASTRAZENECA AB,

*Plaintiffs / Counterclaim-Defendants*

v.

SANDOZ INC. et al.

*Defendants / Counterclaim-Plaintiffs*

)  
)  
)  
)  
) Civil Action No. 1:14-cv-03547 (consolidated)  
)  
) Hon. Renée Marie Bumb, U.S.D.J.  
) Hon. Karen M. Williams, U.S.M.J.  
)  
)  
)  
)

**CORRECTED JOINT STIPULATION  
CONCERNING CLAIM CONSTRUCTION ISSUES**

1. WHEREAS the parties in the above-captioned litigation proposed the following constructions for the claim term “hormonal dependent benign or malignant disease of the breast or reproductive tract” in the March 23, 2015 Joint Claim Construction Statement (D.I. 58) (“JCCS”):

<b>Defendants’ Construction</b>	<b>Plaintiffs’ Construction</b>
<p>Various words or phrases within the claim term have a plain and ordinary meaning. However, the arrangement of the words within this claim term renders the term “benign or malignant disease” to be redundant. To the extent that this term is not redundant, the claim term is indefinite.</p> <p>Moreover, “hormonal dependent” is a term of degree. The Federal Circuit has held that for terms of degree, they must be defined or clarified in the specification or claim to identify more than merely <i>some</i> standard for measuring the scope of the term of degree phrase, and that a failure to do so renders the term indefinite. <i>See Interval Licensing LLC v. AOL, Inc.</i>, 766 F.3d 1364, 1370-71 (Fed. Cir. 2014). Here, the specification and claim renders no guidance as to the scope of hormonal dependency required, instead, it depends on the unpredictable vagaries of any one person’s opinion; therefore, the claim term is indefinite. <i>Id.</i> at 1371.</p>	<p>Plain and ordinary meaning to a person of skill in the art.</p>

2. WHEREAS Defendants clarified in their Joint Opening Markman Brief (D.I. 60) (“Defendants’ Markman Brief”) that: “Defendants do not offer their own construction for the term ‘hormonal dependent benign or malignant disease of the breast or reproductive tract,’ but request that this Court fully reserve the issue and Defendants’ right to move for summary judgment or raise at trial that the phrase renders the claims invalid under § 112 for indefiniteness” and “Defendants submit that these issues should be presented for the Court’s decision on a fully-developed record.”

3. WHEREAS the parties proposed the following constructions for the claim term “administration to a human in need of such treatment” / “a human in need of such treatment” in the JCCS:

<b>Defendants’ Construction</b>	<b>Plaintiffs’ Construction</b>
Plain and ordinary meaning – i.e., administration to a human having a hormonal dependent benign or malignant disease of the breast or reproductive tract.	Plain and ordinary meaning to a person of skill in the art—i.e., administration to a human with a disease (as limited by the claims) that could benefit from the method of treating.

4. WHEREAS on May 7, 2015, Plaintiffs filed the Declaration of John F.R. Robertson, M.D. (D.I. 63-2) (the “Robertson Declaration”) in support of Plaintiffs’ Opening *Markman* Brief (D.I. 63), including in support of Plaintiffs’ proposed constructions for *both* of the above terms (“hormonal dependent benign or malignant disease of the breast or reproductive tract” and “administration to a human in need of such treatment” / “a human in need of such treatment”);

5. WHEREAS Plaintiffs referenced and cited the Robertson Declaration (D.I. 63-2) within Plaintiffs’ Opening *Markman* Brief (D.I. 63);

6. WHEREAS Defendants did not submit an expert declaration in support of their position for *either* of the above terms (“hormonal dependent benign or malignant disease of the

breast or reproductive tract” and “administration to a human in need of such treatment” / “a human in need of such treatment”);

7. WHEREAS, in view of the above, the parties have worked together to attempt to streamline the claim construction process, including claim construction discovery;

8. WHEREAS, the parties agree it is not necessary for the court to construe the term “hormonal dependent benign or malignant disease of the breast or reproductive tract” at this time, and that arguments regarding this term can be postponed to the expert discovery, summary judgment and/or trial phase(s) of the case;

9. WHEREAS, Defendants are willing to forgo the deposition of Dr. Robertson at this time in return for Plaintiffs’ agreement to fully withdraw the Robertson Declaration from the Court’s consideration at this time;

10. WHEREAS Defendants wish to reserve the right to later argue (via expert report, motion for summary judgment and/or at trial) that the term “hormonal dependent benign or malignant disease of the breast or reproductive tract” is indefinite, and Plaintiffs wish to reserve the right to rebut such arguments;

11. WHEREAS Plaintiffs wish to reserve the right to rely on Dr. Robertson during the expert discovery, summary judgment and/or trial phase(s) of the case, including but not limited to arguments relating to the term “hormonal dependent benign or malignant disease of the breast or reproductive tract,” and Defendants wish to reserve all rights to rebut (and depose) Dr. Robertson in connection with said arguments;

12. THEREFORE, the parties agree, subject to the approval of the Court, that:

- a. the term “hormonal dependent benign or malignant disease of the breast or reproductive tract” is hereby removed from the list of terms before the court for construction, and the parties will present no arguments or expert testimony

concerning this term in their July 6, 2015 responsive *Markman* submissions or at the *Markman* hearing currently set for July 23-24, 2015;

- b. the term “administration to a human in need of such treatment” / “a human in need of such treatment” remains in the list of terms before the court for construction, but the parties will not offer any expert testimony with regard to this term in their July 6, 2015 responsive *Markman* briefs or at the *Markman* hearing currently set for July 23-24, 2015;
- c. provided a-b above, the Robertson Declaration (63-2) is hereby removed / stricken from the docket so that it is no longer part of the current claim construction record (such that it will need to be re-filed in order for the Court to consider it in connection with future arguments); and
- d. provided a-b above, Plaintiffs’ May 7, 2015 Opening *Markman* Brief (D.I. 63) is hereby removed / stricken from the docket so that it is no longer part of the current claim construction record, and is replaced with Plaintiffs’ May 22, 2015 Opening *Markman* Brief (D.I. 76), which redacts all citations and references to the Robertson Declaration.

Dated: June 19, 2015

/s/ John E. Flaherty

John E. Flaherty  
Ravin R. Patel  
**McCARTER & ENGLISH LLP**  
Four Gateway Center  
100 Mulberry Street  
Newark, New Jersey 07102  
T: (973) 622-4444  
F: (973) 297-3971

*Of Counsel:*

Lisa B. Pensabene  
Filko Prugo  
Will C. Autz  
Margaret O’Boyle  
Carolyn Wall  
Eberle Schultz  
**O’MELVENY & MYERS LLP**  
7 Times Square  
New York, NY 10036  
T: (212) 326-2000  
F:(212) 326-2061

Dated: June 19, 2015

/s/ Christina L. Saveriano

Eric I. Abraham  
Christina L. Saveriano  
**HILL WALLACK LLP**  
202 Carnegie Center  
Princeton, New Jersey 08540  
T: (609) 924-0808  
F: (609) 452-1888

*Of Counsel:*

William A. Rakoczy  
Paul J. Molino  
Deanne M. Mazzochi  
Rachel P. Waldron  
Cynthia H. Sun  
**RAKOCZY MOLINO MAZZOCHI**  
**SIWIK LLP**  
6 West Hubbard Street  
Chicago, Illinois 60654  
T: (312) 222-6301  
F: (312) 222-6321

*Attorneys for Plaintiffs / Counterclaim-  
Defendants AstraZeneca Pharmaceuticals LP,  
AstraZeneca UK Limited, and AstraZeneca AB*

*Attorneys for Defendant / Counterclaim-  
Plaintiff Sandoz Inc.*

Dated: June 19, 2015

/s/ Michael Rato

George H. Parsells, III  
Michael Rato  
**MCELROY, DEUTSCH, MULVANEY &  
CARPENTER, LLP**  
1300 Mount Kemble Avenue  
P.O. Box 2075  
Morristown, NJ 07962  
T: (973) 993-8100  
F: (973) 425-0161

*Of Counsel:*

Liane M. Peterson (lpeterson@foley.com)  
Debra A. Lange (dlange@foley.com)  
Margareta K. Sorenson (msorenson@foley.com)  
**FOLEY & LARDNER LLP**  
3000 K Street, NW, Suite 600  
Washington, DC 20007  
T: (202) 672-5300  
F: (202) 672-5399

*Attorneys for Defendant / Counterclaim-Plaintiff  
Sagent Pharmaceuticals, Inc. and  
Defendant / Counterclaim-Plaintiff Glenmark  
Generics Inc., USA*

SO ORDERED and SIGNED this 23<sup>rd</sup> day of June, 2015



United States District Court Judge